Insmed Announces Initiation of Phase II Clinical Trial with IPLEX(TM) in Myotonic Muscular Dystrophy

RICHMOND, Va., Nov 05, 2007 (BUSINESS WIRE) -- Insmed Inc. (Nasdaq:INSM), a biopharmaceutical company focused on the development and approval of drugs for the treatment of metabolic diseases with unmet medical needs, today announced the planned initiation of a 24-week, multi-center, randomized, double blind, placebo-controlled Phase II clinical trial with IPLEX(TM) in patients with Myotonic Muscular Dystrophy. The decision to initiate this trial is based on the promising results from an ongoing open-label, dose-escalation trial of IPLEX(TM) in this indication.

Up to 70% of the patients analyzed in an ongoing open-label, dose-escalation trial have reported improvement in one or more of several symptoms commonly associated with Myotonic Muscular Dystrophy, including cognitive function, gastrointestinal function, muscle pain, arm and leg strength, fatigue and endurance. Specific assessment of endurance demonstrated an improved performance in the six minute walk test, a well accepted FDA approval end point. Improvements in endurance were comparable to other drugs approved where this test was used for FDA approval. The six minute walk test is a well accepted, validated, quantitative measure of endurance and has been used as a primary endpoint in pivotal studies of several FDA approved drugs.

The purpose of the Phase II study is to confirm the positive results obtained in the open-label dose escalation trial in a multi-center, randomized, double-blind, placebo-controlled setting. The study will include 60 patients and will be powered to detect a 75 meter difference between IPLEX(TM) and placebo for the change in distance walked during the six minute walk test. The results from this Phase II study will be used to establish the design for Phase III clinical development.

Dr. Geoffrey Allan, Ph.D., Insmed's President and Chief Executive Officer, said, "We are very excited by our initial observations with IPLEX(TM) in the management of this major debilitating condition where there is no effective treatment and we are extremely pleased to announce the initiation of this expanded study. Provided the results of this confirmatory clinical trial replicate those of the ongoing, open-label, dose-escalation study, we believe we will be able to rapidly move IPLEX(TM) into Phase III development for Myotonic Muscular Dystrophy, an indication which we believe represents a significant market opportunity for the company."

About Insmed Incorporated

Insmed is a biopharmaceutical company focused on the development of drug candidates for the treatment of metabolic diseases and endocrine disorders with unmet medical needs. For more information, please visit www.insmed.com.

Forward Looking Statements

This release contains forward-looking statements which are made pursuant to provisions of Section 21E of the Securities Exchange Act of 1934. Investors are cautioned that such statements in this release, including statements relating to planned clinical study design, regulatory and business strategies, plans and objectives of management and growth opportunities for existing or proposed products, constitute forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those anticipated by the forward-looking statements. The risks and uncertainties include, without limitation, risks that product candidates may fail in the clinic or may not be successfully marketed or manufactured, we may lack financial resources to complete development of product candidates, the FDA may interpret the results of studies differently than us, competing products may be more successful, demand for new pharmaceutical products may decrease, the biopharmaceutical industry may experience negative market trends, our entrance into the follow on biologics market may be unsuccessful, our common stock could be delisted from the Nasdaq Global Market and other risks and challenges detailed in our filings with the U.S. Securities and Exchange Commission, including our Quarterly Report on Form 10-Q for the quarter ended June 30, 2007. Readers are cautioned not to

place undue reliance on any forward-looking statements which speak only as of the date of this release. We undertake no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this release or to reflect the occurrence of unanticipated events.
